EXHIBIT B

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

Master File No.
2:12-MD-02327

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

The deposition of LARRY T. SIRLS, II, M.D.,
Taken at 41000 Woodward Avenue, Suite 200 East,
Bloomfield Hills, Michigan,
Commencing at 9:33 a.m.,
Thursday, July 21, 2016,
Before Cheryl McDowell, CSR-2662, RPR.

A. Clinician, medical doctor, academician.
Q. Okay. And it's based largely on your clinical experience, correct?
A. Clinical experience, literature, discussions with friends, colleagues, meetings, et cetera.
Q. And you're not holding yourself out as an expert with regard to the material science of polypropylene, correct?
A. I have done a lot of literature review on the material science. It's very important in my practice because I use these materials, and I would say that I am a clinical expert in the use of these materials, their outcomes, their complications, et cetera.
Q. Okay. Now, you gave a deposition before, correct?
A. Yes.
Q. And have you reviewed that deposition in preparation for your deposition here today?
A. No.

MS. FITZPATRICK: Okay. So why don't we go ahead and mark this as Exhibit 9.

(Sirls TVT-9 marked and attached.)

BY MS. FITZPATRICK:
Q. Go ahead and take a look at that, Doctor. I'd like

Q. Okay. But I'm not asking you whether you're an expert in the use of the products and whether you're an expert in the clinical outcomes and implanting them in women.

Maybe let me ask you this. How many different kinds of polypropylene are there in the world?

A. So polypropylene is a polymer that I want to make sure I understand your question.

Do you mean how many makers are there?

Q. How many different types?

A. I don't understand your question.

Q. Do you know that there's different grades of polypropylene?

A. What do you mean by different grades?

Q. This is what I'm actually trying to get at. It seems to me from your expert report that you are an expert sitting here to tell me about the clinical implications and uses of polypropylene mesh products, particularly the TVT and the TVT-O, in women. That's what I got from your expert report, okay?

What I'm trying to get at is whether you are also an expert on the chemical and physical

properties of polypropylene, polypropylene material generally, not in a clinical setting, but just there's people who specialize in polymers and plastics.

Are you one of those people?

A. I don't specialize in polymers and plastics.

Q. Okay.

A. But I'm informed and educated about many of these issues with polypropylene materials.

Q. Okay. Great. Tell me about the different grades of polypropylene.

A. What I can tell you is that prolene mesh is different than polypropylene because it's treated, right, with antioxidants.

Q. And what are those antioxidants?

A. Santanox and DTL-DP.

Q. And tell me how a manufacturer decides what concentration of antioxidants should be used in a particular polypropylene product.

A. I don't know that.

Q. Okay. Tell me the difference between the polypropylene that is used for an Ethicon product versus a polypropylene that is used for a Boston Scientific product.

A. I don't know that.
Q. Tell me the difference between the polypropylene that's used for an Ethicon product versus an American Medical Systems product.
A. So beyond the weaving, pore size, mesh weight.
Q. So I'm talking about the actual polypropylene.
A. I don't know.
Q. Okay. Do you know whether all mid-urethral slings that are on the market are made with the same base polypropylene?
A. I don't.
Q. Do you know whether all mid-urethral slings that are on the market have the same weave and pore size?
A. They do not.
Q. Okay. What's different between the weave and pore size between the Ethicon TVT and TVT-O and the Boston Scientific mid-urethral slings?
A. The pore size of Ethicon is about thirteen hundred microns. For Boston Scientific it's about a thousand microns. The grams per meter squared for Ethicon is about a hundred. Boston Scientific I think is about eighty-five.
Q. Okay. Now, give it to me for the AMS products.
A. I don't know AMS.

I'm asking you from the purely science background, are you the guy to talk to me about the properties of polypropylene?

A. So there are different levels of properties of polypropylene. I'm not trying to be difficult, but --

Q. You're not going to make your surgery and I'm going to be on my 10:30 flight if we keep going.

You're here to talk about the clinical use of TVT and TVT-O and its clinical outcomes, correct?

A. That's one of the things I talk about, but I'm familiar with the properties of mesh. I've read quite a bit on this.

Q. We'll spend a lot of time on this then. I thought I was going to get you to agree and we would move on, but we'll spend all the time.

Talk to me about where Ethicon gets its polypropylene.

A. From I believe it's a company called Sunoco.

Q. And what is the -- how does it get to Ethicon?

A. I don't know.

Q. Okay. And how does Ethicon treat that polypropylene?

A. To make it prolene? So they have five different materials, and the two of them are antioxidants that I've mentioned to you.

The other three are materials that are not antioxidants. And I don't recall their name, but I'm glad -- I have it in my list of materials that I rely on. I'm glad to look at that.

Q. So tell me, if I am a medical device manufacturer looking to make a polypropylene product, what polypropylene pellets should I choose and why?

A. I don't know that answer.

Q. Okay. If I'm a polypropylene -- if I'm a medical device manufacturer looking to make a polypropylene product, what antioxidants should I choose and why?

A. Well, I've mentioned the antioxidants that they do use.

Q. Okay. I'm asking you, I'm a medical device manufacturer. I'm looking for someone with expertise in material science and polypropylene to help me make a mesh device. You're holding yourself out as such an expert.

I'm asking you what is it, what are the polypropylene -- the antioxidants that I should be looking to add to my mesh devices?

A. So those things I do not know.
Q. Okay. Can you tell me what concentration of antioxidants a medical device manufacturer should add to polypropylene?
A. No, I don't know that.
Q. Can you tell me how a manufacturer should weave its product?
A. So the weave is critical, and there are different ways of doing that.

With regard to pore size?

Q. With regard to the whole thing. I mean, it sounds to me like you know from reading Ethicon's internal documents or whatever else you have that you know some of what Ethicon has used, but you don't know what went into the process to make those choices.

Would that be correct?

A. Some of that information I know and some of it I do not know, correct.
Q. Okay. And that's because you're here to talk to me as a medical physician about the clinical outcomes from the TVT and the TVT-O devices, correct?
A. So I'm here to talk about the tissue response to the mesh.
Q. That would be a clinical outcome, correct?

A. There are basic science things on degradation, et cetera, et cetera, that --

Q. Have you ever researched degradation yourself?

A. So I started looking seriously at degradation when I first heard of it and read everything that I could on it.

Q. Okay.

A. I was exposed to more documents here than those.

Q. Have you ever done primary research by yourself? Because I'll tell you, I've read lots of these documents too and I've read lots of the medical articles. I'm asking you whether beyond reading that stuff, have you ever done primary research into the degradation of polypropylene?

A. I'm sorry. I didn't understand that question. The answer is no.

Q. Have you ever pulled out a microscope and looked at explanted polypropylene devices and studied them for degradation?

A. I've looked at other people's photos of that, but I've not used a microscope myself.

Q. Okay. And whose photos have you looked at?

A. I've looked at many, many photos from different authors. I'm sorry.

BY MS. FITZPATRICK:

Q. Okay. Well, you put a lot of emphasis on what your friends tell you as opposed to the literature and as opposed to information that a medical device manufacturer here, Ethicon, has, correct?

A. I don't agree. I look at all those things.

Q. Okay. So you do consider the literature and you do consider the company-specific information, what's available from the company, right?

A. Those are factors in my decision-making.

Q. Okay. And what information did you receive from Ethicon prior to your use of the TVT-O?

A. Again, I apologize. I don't recall, but it would have been a similar thing. It would have been, you know, cadaver lab, slide decks, handout, IFU, et cetera.

Q. Okay. And you would fully expect that Ethicon would disclose to you the risks it knows are inherent in the TVT-O device and the TVT-O procedure, correct?

A. The things, again, that are unique to the device that are not commonly known that we see with all of our incontinence surgeries.

Q. Okay. Now, how did you surgically treat SUI before you started using the TVT in 2004 and the TVT-O in

A. Some, you know, some differences, but --
Q. Well, we will -- I want to look at some of those in a little bit.
A. Okay.
Q. But before we get there, so you do fascial slings. What retropubic slings do you use?
A. I use the TVT Exact.
Q. And what obturator slings do you use?
A. I use the Abbrevo.
Q. And the Abbrevo is a different or a modified version of the TVT-O, is that right?
A. I look at the Abbrevo as an upgraded product. When you come out, when you have experience and you have time to reflect and think about the technologies, the next generation is often slightly improved over the first. So --
Q. Is the Abbrevo an updated improvement over the traditional TVT-O in your opinion?
A. I like the Abbrevo. It's my sling of choice now for many, many reasons. In fact, it's my primary sling of choice. I prefer that over retropubic slings. But if the Abbrevo were off the market tomorrow and all we had was TVT-O, I would use that.
Q. Okay. Well, let's say how many sling surgeries do

you do a year?

A. I'm not sure. A hundred. I don't know. Two hundred. I'm not sure.

Q. Okay. Let's try to just break it down. How many roughly percentage-wise if you can give me, how many of the slings that you implant are the Abbrevo?

A. So my obturator approach, it's about ninety percent of what I do.

Q. Okay. And about how many are the retropubic?

A. The remaining. Well, maybe nine percent to probably one percent, maybe two percent fascial slings at this time.

Q. Okay. And you agree with me the fascial sling is within the standard of care even though it's not your preferred surgical intervention, correct?

A. Yes.

Q. All right. So you offered a report on the TVT-O specifically.

What are the differences between the TVT-O and the Abbrevo product that you use?

A. So, first of all, let me just qualify that. In our field we tend to -- TVT-O has become kind of a very generic term. So sometimes I'll say TVT-O and what I mean is obturator sling.

Q. Okay.

A. Okay. Just to qualify that.

Q. Okay. That's fair enough.

I want to talk very specifically about not TOT, not the transobturator slings generally but the Ethicon TVT-O device.

A. Okay.

Q. Okay. So the difference between the Ethicon TVT-O device and the Ethicon Abbrevo device.

A. Yes.

Q. What are the differences?

A. The differences are first that the Abbrevos or Abbrevos are all laser-cut mesh.

That's not as important to me clinically. The most important thing to me clinically is it's a shorter length.

Q. And having a shorter length, it doesn't go as far out into the groin and thigh, correct, as the traditional TVT-O?

A. Correct.

Q. Okay. And what in your opinion is the advantage of having the shorter length of the Abbrevo versus the TVT-O?

A. That's actually a really important issue, and the

concern is groin pain, and clinically, I see this very infrequently but I still worry about it because this is a quality of life procedure, and I'm trying to make sure my patients are happy when we're done.

And although I see, again, I would say extremely infrequent groin pain that lasts more than a few weeks, if I can try and minimize that by having a mesh band that does not go through the adductor muscle group, then that's intuitive to me.

Q. Do you believe that the -- so your primary reason is you believe that there's a decrease in the chance of a long-term groin pain in a woman.

Is that sort of my layperson's interpretation of what you're saying?

A. So it was really an intellectual decision because clinically I was not seeing problems with groin pain. I mean, it was very, very infrequent. We talk about it in the literature, we see it in conferences, and it had my attention. The numbers are very low, but I worry about it. You worry. That's what I do.

So when the shorter mesh came out, I looked at it, I said this is logical. Maybe if I have one patient in a thousand who has that

complication and I can prevent that one patient in a thousand from having it, I'd like to do that.

Q. Okay. And is there anything else that recommends the Abbrevo over the TVT-O device to you?

A. No.

Q. Okay. Do you even implant the TVT-O at all, or do you just use the Abbrevo at this point?

A. At this point I use the Abbrevo. If we don't have it, I'll use a TVT-O.

Q. Okay. And when did you change from the TVT-O to the Abbrevo?

A. I'm sorry. I'm not sure. A few years ago, a couple few years ago.

Q. Okay. Now, so a woman comes in to see you and she needs a surgical intervention for stress urinary incontinence. You offer her three potential procedures, the Abbrevo, the TVT Exact, and the fascial sling.

Those are your three options, is that right?

A. Well, there's another surgical option that's periurethral injection.

But we're -- I'm assuming that we're talking about a patient with simple, straightforward

stress incontinence, and if that's the case, those are the three procedures we discuss.

Q. Okay. And why do you use the TVT Exact over just the TVT-O?

A. There's two scenarios where I might do that. Number one is if the patient has had a prior mid-urethral sling, there's some data, not great data, but there's some data that argues that a retropubic vector improves overcomes over the obturator vector in that specific subgroup.

The second reason would be if the patient has dyspareunia or pelvic pain, and what I would do in that patient is on exam, I would feel their pelvic floor muscles, and if they have any evidence of pelvic floor muscle pain or discomfort, I would not use an obturator sling in that patient.

Q. Okay. I think I misspoke. I was going to ask you that question too, so you already gave me that.

Why would you use a TVT Exact over the TVT-R?

A. I thought you said TVT-O.

Q. I apparently did. I just misspoke.

A. Okay.

Q. So --

A. TVT-R. I like the curve of the trocar and the hand movement, but that's personal preference. I've used them both.

Some people really like the big trocar. They feel they can guide it easier and have more control over it. I happen to like the other trocar. It's just personal preference.

Q. Okay. And so let's go back to the question that I asked and you answered. The primary reason -- I just want to get this in my mind. A woman comes in to you for a surgical intervention, okay?

Is your -- generally your first recommendation that they have the Abbrevo sling, and you only go to the TVT Exact or the fascial sling if there's some kind of reason why you don't think that the Abbrevo is particularly suited for that woman, is that right?

A. Yeah. There are a few things that I look at, but if there are none of the risk factors that I am considering, my first choice is an inside-out obturator sling which is the Abbrevo.

Q. Okay. And the risk factors that you discussed were women who already have some type of pelvic floor or pelvic muscle discomfort or dyspareunia, is that

right?

A. Yes.

Q. And is there any other risk factor that you can identify for me that would have you recommend the Exact over the Abbrevo?

A. Yes. That is in a patient who will have had prior mid-urethral sling, and those patients, again, there's some literature, mostly case series and things, not great, no Level I evidence, that argues that the retropubic vector in those patients may be better than the obturator vector, but studies like that, you know, that are not large they've been proven wrong before.

For example, you know, when we looked at the retropubic versus the obturator sling, one of the big issues was if a patient has ISD, if they have severe leakage, is the retropubic sling tighter or not than the obturator, and I have to say I thought that it was, and I was in a group that thought that it was. There's papers that said it was, some papers said that it wasn't.

So when we did our large six hundred patient prospective randomized trial and then we evaluated those patients according to leak point

pressures which is a severity of urethral dysfunction, we found that both slings worked exactly the same.

So that was the first really big study to inform us as a field that the obturator sling works as well as the retropubic sling in patients with severe dysfunction, so that's not something that I use.

Interestingly, when I go to the meetings, everybody at the meetings will say retropubic slings are tighter, and that's because they're not reading the literature.

Q. Okay. So I want to go back to my question. Dyspareunia, pelvic floor muscle dysfunction, that's one risk factor that would have you recommend the TVT-R to a small subgroup of your -- subpopulation of your patients, right?

A. So the retropubic sling instead of an obturator?

Q. Right. Prior mid-urethral sling, you would go to a retropubic over the obturator in that case, correct?

A. For now until that's proven to be wrong.

Q. Okay. Anything else, any other risk factors that would have you recommend to a woman that she have a retropubic as opposed to an Abbrevo device?

A. Nothing that I can think of right now.
Q. Okay. And then you also do a very small number of fascial slings, is that correct?
A. Yes.
Q. Are those ever -- do you ever recommend a fascial sling to a patient?
A. I do.
Q. Okay. And in what candidates would you recommend a fascial sling or a polypropylene mid-urethral sling?
A. So the brilliant thing about the mid-urethral sling is that it's tension free. That was just a critical advance, and it's changed. It's been the single most important thing that has improved the side effect profile of these procedures.

The fascial slings are placed at the bladder neck, not the mid-urethra, and historically they have been what we call compressive and which means obstructive which means that the patients have higher urgency rates and higher UTI rates, all of which are proven in the literature.

So when I have a patient whose urethra is mobile, it's moving, then I can put a mid-urethral sling in them. The urethra moves, hits the sling, and it works. Dynamic kinking is what we would call

rates with those.

Q. Do you tell your patients that there's a potential for long-term complications associated with the use of the Exact device?

A. So, again, I tell my patients that we're putting in a permanent material and that there are the complications we've discussed.

The long-term complications that I see in my practice are, again, the very, very rare mesh exposure. Pain is something we see acutely. I don't see pain change at two and three and four years.

We talk about urgency, again, and dyspareunia. Urgency is probably the most important symptom. Urgency is associated with all the bad outcomes.

Q. Okay. Let me talk to you a little bit about something you raised earlier which is laser cut versus mechanically cut.

Do you have a preference between laser-cut and mechanical-cut products?

A. Absolutely not. In fact, I really was not aware that it was such a hot topic until I reviewed these internal documents. I was not aware of any of that.

A. It makes no difference to me.
Q. Has Ethicon ever told you that there are different risk profiles for the TVT mechanical-cut and the TVT laser-cut meshes?
A. So when we were discussing the sling choices when we were going to do our NIH-funded trial, we did discuss that issue, and we felt at that time, all the primary investigators felt that it was not an issue that we needed to -- that would influence our decision. I don't recall anything from Ethicon. I recall things at meetings.

But most of the stuff that I've seen really comes from these binders because clinically, yeah, the stress incontinence mesh document binders, because clinically, I just, I've used both, and I just don't see any clinical difference. So in my mind, it's just not important.
Q. Okay. So prior to working as an expert for Ethicon, looking at these internal Ethicon documents, you were not aware of any internal documents, debate, anything at Ethicon concerning different risk profiles between a laser-cut mesh and mechanical-cut mesh, correct?
A. The only thing I was aware of is what we discussed

believe that the Instructions For Use that are provided with the Ethicon products are valuable tools for physicians, correct?

A. They're one piece of information that a physician would consider.

Q. Okay. And is it your opinion, Doctor Sirls, that the TVT IFU prepared by Ethicon prior to 2015 was adequate to advise physicians on the risks associated with the TVT device?

And, you know, I don't want you guessing blind, so let me go ahead and mark this as Exhibit 11 which is the pre-2015 IFU for the Gynecare TVT.

(Sirls TVT-11 marked and attached.)

THE WITNESS: I'm sorry. What is the question again?

BY MS. FITZPATRICK:

Q. Is it your opinion that this IFU for the Gynecare TVT which was prepared by Ethicon prior to 2015 was adequate to advise physicians on the risks associated with the TVT device?

A. So the information that is provided in this IFU is intended to augment the physician's knowledge base, and I think that the four things listed here are

things that are informative.

Q. Okay. But I'm asking you a different question, so let's focus on that.

A. Okay.

Q. I'm not asking you whether it's informative. What I'm asking you, is it your opinion that this IFU that predates 2015 for the Gynecare TVT was adequate to advise physicians of the risks associated with the TVT device?

A. As a pelvic surgeon, I know all of these things. So these things, this is adequate for me because my knowledge base augments and supersedes this information. So I find this to be adequate.

Q. Okay. Are you speaking only for yourself based on your knowledge base?

A. Myself, my partners, my fellows, my residents. I mean, those of us who do this know this.

Q. But you realize there's lots of doctors who implant the TVT that go beyond you, your partners, your fellows, and your residents, right?

A. Sure.

Q. A whole lot of doctors around this country who are implanting and have implanted the TVT device into women?

A. Yes.
Q. Okay. Do you believe as a general proposition that this Gynecare TVT IFU from pre-2015 was adequate to warn physicians, all the physicians who are implanting TVT devices into women, of the risks associated with the TVT device?
A. Yes.
MS. FITZPATRICK: Okay. And let's take a look then, we'll mark this as Exhibit 12.
(Sirls TVT-12 marked and attached.)
BY MS. FITZPATRICK:
Q. The Gynecare TVT Obturator System Instructions For Use that Ethicon put out prior to 2015.
You've seen this document before, right?
A. Yes.
Q. And is it your opinion, Doctor Sirls, that the TVT IFU prepared by Ethicon prior to 2015 was adequate to advise physicians as a whole on the risks associated with the TVT device?
A. Yes. It's the same adverse reaction list.
Q. Okay. Now, I want you to put Exhibits 10, 11, and 12 in front of you.
A. Okay.
Q. And we discussed at page eleven of Doctor Schimpf's

that.

When you look at the risks associated with the TVT device in the 2015 IFU, do those contain newly identified risks, that is things that you and fellow researchers have discovered are risks associated with the TVT device from the clinical literature, or are those risks that everybody's always known anyhow?

A. Do you mind if I look at them?

Q. Absolutely, please do.

A. The first one, punctures, lacerations, vessels, nerves, et cetera, that's with any surgery that we do. Transitory local irritation, any surgery that I do. As with any implant, foreign body response may occur. Extrusion, erosion, exposure, any surgery that we do. I would do fascial slings with cadaver fascia or porcine dermis, and I could have exposure. As with all procedures, risk of infection. Again, that's not limited to these procedures.

Overcorrection, that's --

Q. Wait. You skipped mesh extrusion, exposure, and erosion into the vagina or other structures.

That's unique to mesh?

A. I apologize. I did skip that, and you're correct.

THE WITNESS: So my understanding when you look at both federal regulations and guidelines on IFUs, it has to be something that is unique, that is unique to the procedure and not commonly known.

And that's kind of where the whole argument is here is that these things are commonly known. The only thing that is unique here are the ones that specifically deal with mesh. We know removing it's hard, but mesh exposure is unique to these products, yes.

BY MS. FITZPATRICK:

Q. It's not my question.

A. I'm sorry.

Q. Is there any reason based on your medical knowledge and your clinical knowledge, is there any reason why any or all of these adverse reactions that are identified in the 2015 IFU could not have been listed in the pre-2015 IFU? Are these new things that people didn't know about until 2015?

MR. KOOPMANN: Object to form.

THE WITNESS: So I can't really comment on what the people at Ethicon were thinking when they --

vector can -- the sling may roll if you're not careful in your tensioning. So if you put it under too much tension, it's going to pull, it can pull proximally.

Q. Okay.

A. And I look at that as a technical problem.

Q. Okay.

A. Technical placement.

Q. So it can curl when a physician is off in the art of tensioning, correct?

A. If they put it under too much tension.

No, I think those are two different arts. I can obstruct a patient with a perfectly placed sling that is not curled. I think that curling is a degree beyond appropriate tensioning.

So obstruction with a nice flat sling is possible. Curling in my mind typically means it's too tight.

Q. Okay. So all I had asked you is you agree with me that a TVT or TVT-O device can curl under what you say is when it's too tight, is that right?

A. If it's placed inappropriately, it can curl, sure.

Q. Okay. And when you say that's inappropriate, would that be malpractice by a surgeon?

A. I would not think that would be malpractice.
Q. Okay. Would it be -- would a physician have fallen below the standard of care in treating his or her patient if the TVT or TVT-O device curled in their patient?
A. I would not think it's below the standard of care.
Q. Okay. And are the TVT-O, TVT or TVT-O devices intended to fray?
A. Intended to fray?
Q. Right, designed or intended to fray.
A. So the fraying that we see is primarily from too much tension. When you look at the amount of force required to denature, change the contour, it's typically over four or five newtons. So in use in a female body, it should not fray if they're under the correct tension.
Q. Okay.
A. So it's not designed to fray, no.
Q. Okay. But it can fray according to what you just said if it's not under the correct tension, correct?
A. If you take a sling and you put it under tension, you can change the characteristics of the sling.
Q. Okay. Including it can fray then, right?
A. Define for me fray. I want to make sure I

understand what you're saying.

Q. Unravel at the edges.

A. Unravel at the edges. I don't know about unraveling at the edges. When I see it, you can stretch it out and have a contour like a wasting.

I don't know if that's unraveling at the edges, but I can see a contour change.

Q. Have you seen any internal Ethicon documents documenting that the TVT and TVT-O meshes can fray?

A. I apologize. I don't recall the term fray. I'm struggling with that. I know I've seen a lot of documents on forces applied, stretching, things like that. And it's typically in, you know, the unrealistic forces.

Q. Okay. So you don't actually know what fraying is?

A. I just want to make sure that we're speaking the same language.

Q. So you don't know what it is, is that right?

A. Well, fraying I could understand, you know, if my shirt's wearing out, the edge here would fray, I get that, and I see that that's what you're saying about the material now.

But clinically, I don't see fraying because I don't put it under tension.

Q. Okay. I'm asking you a different question, Doctor. And I think you already gave me this answer, so I'm not sure whether you're walking the answer back or whether it's changed.

I thought that you had told me that the TVT and TVT-O devices can fray if they're placed under excessive tension.

A. And then I want to just understand what you meant about fraying. I'm talking about a contour change. It's wide, it gets narrow, it gets wide again.

Q. Okay.

A. I have not looked at those edges with magnification to see if it's unraveling --

Q. Okay.

A. -- which is my interpretation of fraying.

Q. Fair enough.

But that contour change, we'll use the word contour change, can occur. It's not designed to occur but it can occur with the TVT and TVT-O devices?

A. Any of these meshes if you pull on them hard enough, you're going to potentially damage it.

Q. Are either the TVT or the TVT-O devices designed to release particles?

Q. And it was specifically studying the difference not between the trocar or the different trocars in the TVT-R or the TVT Exact, but it was instead studying the difference in the mechanically cut mesh versus the laser-cut mesh, is that right?

A. Yes.

Q. Okay. Let's go back to these Exhibits 4 and 5, and I'm going to talk about the internal documents. I know there's some publicly available documents in here but specifically the internal documents in there.

Were those documents selected for you by Ethicon's lawyers?

A. Yes.

Q. Okay. Did you specifically ask Ethicon's lawyers for any additional documents from them after they had provided you with the initial set?

A. No.

Q. Okay. And they were hand-selected by lawyers.

Are there any parameters you gave them about what particular kind of documents you wanted to see?

A. I think they were trying to help me understand the thought process that Ethicon was going through when

they were looking at the issues that we're discussing.

I did not request, I did not lay out parameters of what I wanted. I wanted mesh degradation stuff, and they provided that as well.

Q. Okay. But is it fair to say that the internal company documents that you reviewed are documents that were selected by lawyers as opposed to documents that you selected from a bigger body of documents that were available to you?

A. That's not practical really because these are thousands of pages of documents, and I'm not going to review five thousand pages and ask for at least fifteen hundred. I don't have time to do that.

Q. Okay.

A. So I depended on them.

Q. Okay. You depended on them to do that for you?

A. Yeah.

Q. Let's talk about some of the complications associated.

In your clinical practice, have you treated women who have new onset dyspareunia following the implant of a TVT or TVT-O device?

A. Yes.

Q. Okay. In your practice have you treated women for whom the TVT-O or the TVT-R failed and they had recurrent or continued stress urinary incontinence?

A. Yes.

Q. In your practice have you treated women with the TVT or TVT-R who had mesh exposure or erosion into the vagina?

A. Yes.

Q. And in your practice have you treated women who have a TVT-R or TVT-O who have a mesh erosion into the urethra?

A. Yes.

Can I back up? You're saying either/or?

Q. Either/or, yeah.

A. Yes.

Q. Yeah.

Have you treated women with either a TVT or a TVT-O who had mesh erosion or exposure into the bladder?

A. Yes.

Q. Okay. Have you had to perform reoperations on women who had a TVT-O or TVT-R procedure?

A. Yes.

Q. Have you ever had to remove a TVT device from a

woman?

A. What do you mean by remove? How much of the device are we talking about?

Q. Any portion of the device.

A. Sure.

Q. Okay. And how many surgeries have you performed where you have removed a portion of a TVT device?

A. I don't know.

Let me qualify this by saying that at Beaumont, we control this area, and we set up privileges in 2006 limiting who can implant. So we basically own the area, and we just don't see as much trouble as other people see.

I'm going to guess twenty or thirty times.

Q. And that's the TVT or the --

A. That's any TVT, O, R, mesh exposure, urethra, bladder, anything.

Q. Okay. And those would all be patients in who you have implanted the TVT or someone in your practice has implanted the TVT?

A. Some of them.

Q. Someone in your practice has implanted the TVT or the TVT-O device, is that right?

the adverse reaction section.

Do you recall that?

A. Yes.

Q. Right above the adverse reaction section, there's a section that says warnings and precautions, is that right?

A. Yes.

Q. And if you look at the fifth bullet point from the bottom of that list of warnings and precautions, it says: Transient leg pain lasting twenty-four to forty-eight hours may occur and can usually be managed with mild analgesics, is that correct?

A. Correct, yes.

Q. And then if you look at the Exhibit 11 which is the TVT IFU, before 2015, you don't see that same notation of transient leg pain, do you?

A. That's correct.

Q. So in that respect, would you agree that these TVT and TVT-O IFUs before 2015 do set forth a different risk profile?

MS. FITZPATRICK: Objection.

THE WITNESS: Yeah. I apologize for that. I will tell you that the print is so small, I can hardly see it even with my glasses on.